DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

NeuWave Medical, Inc.
% Mr. Dan Kosednar
Director of Regulatory Affairs and Quality Assurance
3529 Anderson Street
MADISON WI 53704

July 9, 2015

Re: K150313
Trade/Device Name: Ablation Confirmation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 15, 2015
Received: June 16, 2015

Dear Mr. Kosednar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K150313

Device Name
Ablation Confirmation™

Indications for Use *(Describe)*
Ablation Confirmation™ (AC), is a Computed Tomography (CT) image processing software package available as an optional feature for use with the Certus® 140 2.45 GHz Ablation System. AC is controlled by the user via an independent user interface on a second monitor separate from the Certus 140 user interface. AC imports images from CT scanners and facility PACS systems for display and processing during ablation procedures. AC assists physicians in identifying ablation targets, assessing proper ablation probe placement and confirming ablation zones. The software is not intended for diagnosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

| | |
|---|---|
| Date: | 07/09/2015 |
| Subject: | 510(k) Summary of Safety and Effectiveness Information for NeuWave Medical's Ablation Confirmation™ image processing software |
| Company: | NeuWave Medical, Inc.<br>3529 Anderson Street<br>Madison, WI 53704 |
| FDA Establishment# | 3008769756 |
| Contact: | Dan Kosednar, Director of Regulatory Affairs and Quality Assurance<br>P – 608-512-1592<br>F – 608-512-1509 |
| Proprietary:<br>Classification: | Ablation Confirmation™ Common: Computed Tomography X-ray System<br>Radiology, JAK, 21 CFR 892.1750 |

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992.

**Predicate Devices**

Ablation Confirmation™ is substantially equivalent to the following currently marketed device:

- Perfint Maxio – Class II – 21CFR892.1750 which has been the subject of a cleared 510(k) with the FDA log number K132108.

**Indications For Use**

Ablation Confirmation™ (AC), is a Computed Tomography (CT) image processing software package available as an optional feature for use with the Certus® 140 2.45 GHz Ablation System. AC is controlled by the user via an independent user interface on a second monitor separate from the Certus 140 user interface. AC imports images from CT scanners and facility PACS systems for display and processing during ablation procedures. AC assists physicians in identifying ablation targets, assessing proper ablation probe placement and confirming ablation zones. The software is not intended for diagnosis.

**Device Description**

AC is resident on the Certus® 140 system and is accessible to the physicians via a second, dedicated monitor with its own user interface separate from the ablation user interface. AC functions are controlled via a USB connected mouse. AC connects to a facility PACS system and CT scanner and receives and sends CT and MR images via the DICOM protocol.

AC contains a wide range of image processing tools, including:

- 2D image manipulation
- 3D image generation (from 2D images)
- 3D image manipulation
- Region of interest (ROI) identification, segmentation and measurement
- Automatic identification of ablation probes
- Registration of multiple images into a single view

Prior to an ablation procedure, physicians can use AC to semi-automatically segment and visualize ablation target lesions in soft tissue including liver, lung and kidney. The physician initiates the segmentation with tools provided on the screen. AC then uses segmentation algorithms to construct a 2-D visualization of the target lesion selected. The physician can accept the initial segmentation results or use AC tools to manually adjust the defined target lesion. Once accepted, the identified target is rendered into a 3D image.

Upon the placement of ablation probes, taking and importing the CT scan, AC can process the image and identify up to three ablation probes. AC can then perform a registration of the initial CT scan, containing the identified target with the second scan containing the ablation probe(s) in place. The resulting image allows the physician to visualize the ablation probe(s) in relation to the identified target. This enables physicians to ensure proper probe(s) placement prior to starting the ablation. Following the ablation procedure and a post-procedure CT scan, AC allows the physician to semi-automatically segment and visualize the ablation zone using the same process as in the initial target segmentation. AC can then performs a registration of the initial CT scan, containing the identified target, with the final CECT scan containing the segmented ablation zone. The resulting image set includes the ablation zone overlaid onto the initial target lesion segmentation to help physicians determine the technical success (ablation zone covers target lesion with desired amount of margin) of the ablation procedure.

All AC processing and viewing is accomplished at the Certus® 140 Ablation System without the physician having to leave the procedure area to utilize separate image processing tools.

Additionally, AC allows for the images to be viewed by a remote physician for time-saving clinical consultation on the current procedure.

**Performance Data**

Ablation Confirmation™ was tested in accordance with a test plan that fully evaluated all functions performed by the software. The system passed all pre-determined acceptance criteria identified in the test plan.

Verification and validation testing were completed in accordance with the company's Design Control process in compliance with 21 CFR Part 820.30, which included testing that fulfills the requirements of FDA "Guidance on Software Contained in Medical Devices". Potential risks were analyzed and satisfactorily mitigated in the device design.

Segmentation and Registration accuracy were demonstrated through adequate bench testing and also through clinical experience of qualified users. Testing was performed using retrospectively obtained CT image series from ablation procedures.

**Comparison to Predicate**

AC is similar to the predicate as both system contain image processing tools designed for use in procedures that involve the use of rigid straight instruments, including ablation probes used in thermal ablation procedures. All key image processing functions performed by AC are also performed by the predicate. Some of the features and installation requirements on the predicate are not functions or requirements of AC. These include: 1: all aspects associated with the stereotactic instrumentation used to plan for and help position rigid instruments prior to the user advancing them into the patient; and 2: a separate, large footprint system to be in the already space constrained CT suite which is required with the predicate.

**Substantial Equivalence Discussion**

Ablation Confirmation™ is substantially equivalent in design concepts, technologies and materials to the image processing aspects of the identified predicate. AC does not present any new questions of safety or effectiveness.